



Louisiana

Open and Thoracoscopic Approaches to Treat Atrial Fibrillation and Atrial Flutter (Maze and Related Procedures)

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 09/14/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Catheter Ablation as Treatment for Atrial Fibrillation is addressed separately in medical policy 00267.

Note: Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation is addressed separately in medical policy 00296.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the maze or modified maze procedure, performed on a non–beating heart during cardiopulmonary bypass with concomitant cardiac surgery for treatment of symptomatic atrial fibrillation (AF) or flutter to be **eligible for coverage.****

When Services Are Considered Not Medically Necessary

The use of an open maze or modified maze procedure performed on a non–beating heart during cardiopulmonary bypass without concomitant cardiac surgery for treatment of atrial fibrillation (AF) or flutter to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

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Based on review of available data, the Company considers stand-alone minimally invasive, off-pump maze procedures (ie, modified maze procedures), including those done via mini-thoracotomy for treatment of atrial fibrillation (AF) or flutter to be **investigational**.*

Based on review of available data, the Company considers hybrid ablation (defined as a combined percutaneous and thoracoscopic approach) for the treatment of atrial fibrillation (AF) or flutter to be **investigational**.*

Based on review of available data, the Company considers the maze or modified maze procedures for any indication not listed above to be **investigational**.*

Policy Guidelines

Given the availability of less-invasive alternative approaches to treat atrial fibrillation performing the maze procedure without concomitant cardiac surgery should rarely be needed.

Published studies on the maze procedure have described patients with drug-resistant AF and atrial flutter as having experienced their arrhythmias for an average of 7 or more years and having had unsuccessful results with an average of 5 or more antiarrhythmic medications.

Background/Overview

Atrial Fibrillation

Atrial Fibrillation (AF) is a supraventricular tachyarrhythmia characterized by disorganized atrial activation with ineffective atrial ejection. The underlying mechanism of AF involves the interplay between electrical triggering events that initiate AF and the myocardial substrate that permits propagation and maintenance of the aberrant electrical circuit. The most common focal trigger of AF appears to be located within the cardiac muscle that extends into the pulmonary veins. The atria are frequently abnormal in patients with AF and demonstrate enlargement or increased conduction time. Atrial flutter is a variant of AF.

Treatment

The first-line treatment for AF usually includes medications to maintain sinus rhythm and/or control the ventricular rate. Antiarrhythmic medications are only partially effective; therefore, medical

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treatment is not sufficient for many patients. Percutaneous catheter ablation, using endocardial ablation, is an accepted second-line treatment for patients who are not adequately controlled on medications and may also be used as first-line treatment. Catheter ablation is successful in maintaining sinus rhythm for most patients, but long-term recurrences are common and increase over time. Performed either by open surgical techniques or thoracoscopy, surgical ablation is an alternative approach to percutaneous catheter ablation.

Open Surgical Techniques

The classic Cox maze III procedure is a complex surgical procedure for patients with AF. It involves sequential atriotomy incisions that interrupt the aberrant atrial conduction pathways in the heart. The procedure is also intended to preserve atrial pumping function. It is indicated for patients who do not respond to medical or other surgical antiarrhythmic therapies and is often performed in conjunction with correction of structural cardiac conditions such as valve repair or replacement. This procedure is considered the criterion standard for the surgical treatment of drug-resistant AF, with a success rate of approximately 90%.

The maze procedure entails making incisions in the heart that:

- direct an impulse from the sinoatrial node to the atrioventricular node;
- preserve activation of the entire atrium; and
- block re-entrant impulses responsible for AF or atrial flutter.

The classic Cox maze procedure is performed on a nonbeating heart during cardiopulmonary bypass. Simplification of the maze procedure has evolved with the use of different ablation tools such as microwave, cryotherapy, ultrasound, and radiofrequency energy sources to create the atrial lesions instead of employing the incisional technique used in the classic maze procedure. The Cox maze IV procedure involves the use of radiofrequency energy or cryoablation to create transmural lesions analogous to the lesions created by the "cut-and-sew" maze.

Minimally Invasive (Thoracoscopic) Techniques

Less invasive, transthoracic, endoscopic, off-pump procedures to treat drug-resistant AF have been developed. The evolution of these procedures involves both different surgical approaches and different lesion sets. Alternative surgical approaches include mini-thoracotomy and total thoracoscopy with video assistance. Open thoracotomy and mini-thoracotomy employ

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cardiopulmonary bypass and open-heart surgery, while thoracoscopic approaches are performed on the beating heart. Thoracoscopic approaches do not enter the heart and use epicardial ablation lesion sets, whereas the open approaches use either the classic "cut-and-sew" approach or endocardial ablation.

Lesion sets may vary independent of the surgical approach, with a tendency toward less extensive lesion sets targeted to areas most likely to be triggers of AF. The most limited lesion sets involve pulmonary vein isolation and exclusion of the left atrial appendage. More extensive lesion sets include linear ablations of the left and/or right atrium and ablation of ganglionic plexi. Some surgeons perform left atrial reduction in cases of left atrial enlargement.

The type of energy used for ablation also varies; radiofrequency energy is most commonly applied. Other energy sources such as cryoablation and high-intensity ultrasound have been used. For our purposes, the variations on surgical procedures for AF will be combined under the heading of "modified maze" procedures.

Hybrid Techniques

"Hybrid" ablation refers to the use of both thoracoscopic and percutaneous approaches in the same patient. Ablation is performed on the outer surface of the heart (epicardial) via the thoracoscopic approach, and on the inner surface of the heart (endocardial) via the percutaneous approach. The rationale for a hybrid procedure is that a combination of both techniques may result in a complete ablation. Thoracoscopic epicardial ablation is limited by the inability to perform all possible ablation lines because the posterior portions of the heart are not accessible via thoracoscopy. Percutaneous, endoscopic ablation is limited by incomplete ablation lines that often require repeat procedures. By combining both procedures, a full set of ablation lines can be performed, and incomplete ablation lines can be minimized.

The hybrid approach first involves thoracoscopy with epicardial ablation. Following this procedure, an electrophysiologic study is performed percutaneously followed by endocardial ablation as directed by the results of electrophysiology. Most commonly, the electrophysiology study and endocardial ablation are done immediately after the thoracoscopy as part of a single procedure. However, some hybrid approaches perform the electrophysiology study and endocardial ablation on separate days, as directed by the electrophysiology study.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several radiofrequency ablation systems have been cleared for marketing by the U.S. FDA through the 510(k) process for cardiac tissue ablation (product code OCL). Table 1 provides a select list.

Table 1. Radiofrequency Ablation Approved by the U.S. Food and Drug Administration

Device	Manufacturer	510(k) Date	510(k) number
Cobra Fusion Ablation System	AtriCure	Feb 2019	K190151
Medtronic Cardioblate [®] ‡ System	Medtronic	Jan 2002	K013392
Cardima Ablation System	Cardima	Jan 2003	K022008
Epicor [™] ‡ Medical Ablation System	Epicor Medical	Feb 2004	K022894
Isolator [™] ‡ Transpolar [™] ‡ Pen	AtriCure	Jun 2005	K050459
Estech COBRA [®] ‡ Cardiac Electrosurgical Unit	Endoscopic Technologies	Jan 2006	K053326
Coolrail [™] ‡ Linear Pen	AtriCure	Mar 2008	K073605
Numeris [®] ‡ Guided Coagulation System with VisiTrax [®] ‡	nContact Surgical	Feb 2009	K090202
EPi-Sense [®] ‡ Guided Coagulation System with VisiTrax [®] ‡	nContact Surgical	Nov 2012	K120857

A number of cryoablation systems, which may be used during cardiac ablation procedures, have also been cleared for marketing, including those in Table 2.

Table 2. Cryoablation Systems Approved by the U.S. Food and Drug Administration

Device	Manufacturer	510(k) Date
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Cryocare [®] ‡ Cardiac Surgery System	Endocare	Mar 2002
SeedNet [™] ‡ System	Galil Medical	May 2005
SurgiFrost [®] ‡ XL Surgical CryoAblation System	CryoCath Technologies; now Medtronic	Jul 2006
Isis [™] ‡ cryosurgical unit	Galil Medical	Mar 2007

Rationale/Source

There are various surgical approaches to treat atrial fibrillation (AF) that work by interrupting abnormal electrical activity in the atria. Open surgical procedures, such as the Cox maze procedure were first developed for this purpose and are now generally performed in conjunction with valvular or coronary artery bypass graft surgery. Surgical techniques have evolved to include minimally invasive approaches that use epicardial radiofrequency ablation, a thoracoscopic or mediastinal approach, and hybrid catheter ablations/open procedures.

For individuals who have symptomatic AF or flutter who are undergoing cardiac surgery with bypass who received a Cox maze or a modified maze procedure, the evidence includes several randomized controlled trials (RCTs) and nonrandomized comparative studies, along with systematic reviews of these studies. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. Several small RCTs have provided most of the direct evidence confirming the benefit of a modified maze procedure for patients with AF who are undergoing mitral valve surgery. These trials have established that the addition of a modified maze procedure results in a lower incidence of atrial arrhythmias following surgery, with minimal additional risks. Observational studies have supported these RCT findings. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have symptomatic, drug-resistant AF or flutter who are not undergoing cardiac surgery with bypass who receive minimally invasive, off-pump thoracoscopic maze procedures, the evidence includes RCTs and observational studies, some of which identify control groups. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. Most of the direct evidence comparing surgical AF ablation with percutaneous catheter ablation comes from one RCT

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(FAST) that used video-assisted thoracoscopy in patients with antiarrhythmic drug-refractory atrial fibrillation with left atrial dilatation and hypertension, 67% of which had previously failed CA. In FAST, at one year, thoracoscopic ablation had higher success at maintaining sinus rhythm (36.5% for CA and 65.6% for surgical ablation), but also reported higher adverse event rates compared with CA. At 7 years, outcomes were consistently improved with thoracoscopic ablation, but interpretation of those findings is limited by important flaws in study conduct. In contrast, findings from a small single-center RCT in patients with no previous CA suggested no significant benefit with minimally invasive thoracoscopic ablation and more major complications. The case series have generally reported high success rates, and a few with matched comparison groups have reported higher success rates with surgical treatment than with catheter ablation. However, most series lacked a control group, generally only reported short-term outcomes, and did not consistently report adverse events. Therefore, this evidence does not permit definitive conclusions whether a specific approach is superior to the other. Factors, such as previous treatment, the probability of maintaining sinus rhythm, the risk of complications, contraindications to anticoagulation, and patient preference, may all affect the risk-benefit ratio for each procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have symptomatic, drug-resistant AF or flutter who are not undergoing cardiac surgery with bypass who receive hybrid thoracoscopic and endocardial ablation procedures, the evidence includes a nonrandomized comparative study and single-arm case series. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. The studies have suggested that hybrid ablation procedures are associated with high rates of freedom from AF; but direct comparisons with catheter ablation are lacking. Comparative studies are needed to permit direct comparisons of the benefits and harms of hybrid ablation procedures with alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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2013 Input

In response to requests, input was received from 2 physician specialty societies and 6 academic medical centers (4 reviewers) while this policy was under review in 2013. There was consensus on the medically necessary statements. For subgroups of populations (eg, those who have failed percutaneous catheter ablation), there was mixed support without consensus. There was also mixed support for the use of hybrid ablation.

2010 Input

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers (4 reviewers) while this policy was under review in 2010. There was unanimous support for the policy statement regarding with cardiopulmonary bypass maze procedure. There was mixed support for the policy statement on off-bypass (off-pump) maze procedure; some providing input indicated off-pump procedures might be useful in select patients (eg, those who cannot tolerate anticoagulation). Several providing input also commented on the limited long-term data for off-pump procedures.

Practice Guidelines and Position Statements

Society of Thoracic Surgeons

In 2017, the Society of Thoracic Surgeons published guidelines on the surgical treatment of atrial fibrillation (AF). Recommendations are provided in see Table 3.

Table 3. Guidelines on Surgical Treatment of Atrial Fibrillation

Recommendation	COR	LOE
Surgical ablation for AF is recommended at the time of concomitant mitral operations to restore sinus rhythm.	I	A
Surgical ablation for AF is recommended at the time of concomitant isolated aortic valve replacement, isolated CABG surgery, and aortic valve replacement plus CABG operations to restore sinus rhythm.	I	B

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Surgical ablation for symptomatic AF in the absence of structural heart disease that is refractory to class I/III antiarrhythmic drugs or catheter-based therapy of both is reasonable as a primary stand-alone procedure to restore sinus rhythm.	IIa	B
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AF: atrial fibrillation; CABG: coronary artery bypass graft; COR: class of recommendation; LOE: level of recommendation.

American Heart Association et al

In 2019, the American Heart Association, American College of Cardiologists, and Heart Rhythm Society issued joint guidelines in collaboration with the Society of Thoracic Surgeons on the management of patients with AF. Recommendations on the use of surgical ablation to maintain sinus rhythm are provided in Table 4.

Table 4. Guidelines on the Management of Atrial Fibrillation

Recommendation	COR	LOE
" AF catheter ablation may be reasonable in selected patients with symptomatic AF and HF with reduced left ventricular (LV) ejection fraction (HFrEF) to potentially lower mortality rate and reduce hospitalization for HF (S6.3.4-1, S6.3.4-2)."	IIb	B-R

AF: atrial fibrillation; COR: class of recommendation; LOE: level of recommendation.

Heart Rhythm Society et al

A 2017 expert consensus statement was developed by the Heart Rhythm Society, European Heart Rhythm Association, and European Cardiac Arrhythmia Society. The statement was endorsed by four other cardiology associations. Recommendations on concomitant surgical ablation in patients undergoing cardiac surgery for other purposes and who have symptomatic AF are provided in Table 5.

Table 5. Guidelines on Concomitant Surgical Ablation in Patients Undergoing Cardiac Surgery^a

Recommendation	COR	LOE
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Paroxysmal: Surgical ablation is recommended for patients undergoing surgery for other indications	II	B-NR
Persistent: Surgical ablation is recommended for patients undergoing surgery for other indications	II	B-NR
Longstanding Persistent: Surgical ablation is recommended for patients undergoing surgery for other indications	II	NR

COR: class of recommendation; LOE: level of recommendation; NR: nonrandomized.
 a: For patients with symptomatic AF prior to initiation of antiarrhythmic therapy with Class I or III antiarrhythmic medication and indication for concomitant closed surgical ablation for AF, paroxysmal, persistent, and long-standing persistent is reasonable (Class: IIa; LOE: B-NR).

The following recommendations were made on stand-alone surgical ablation in patients with symptomatic AF refractory or intolerant to at least one class 1 or 3 antiarrhythmic medication (see Table 6).

Table 6. Guidelines on Stand-Alone Surgical Ablation for Symptomatic AF trial Fibrillation Refractory to Antiarrhythmics

Recommendation ^a	COR	LOE
Paroxysmal		
Stand alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach	IIb	B-NR
Stand alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation	IIb	B-NR
Persistent		
Stand alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach	IIa	B-NR
Stand alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation	IIa	B-NR

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Longstanding persistent		
Stand alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach	IIb	B-NR
Stand alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation	IIb	B-NR

COR: class of recommendation; LOE: level of recommendation; NR: nonrandomized. a: The recommendations noted that "it might be reasonable to apply the indication for stand-alone surgical ablation described above to patients being considered for hybrid surgical AF ablation.

American Association for Thoracic Surgery

In 2017, the American Association for Thoracic Surgery published guidelines on surgical ablation for AF. Recommendations on concomitant surgical ablation in patients with AF are provided in Table 7.

Table 7. Guidelines on Concomitant Surgical Ablation in Patients with Atrial Fibrillation

Recommendation	COR	LOE
"Addition of a concomitant surgical ablation procedure for AF does not increase the incidence of perioperative morbidity."		IIa A, B-R, B-NR ^a
"Addition of a concomitant surgical ablation procedure for AF does not change the incidence of perioperative stroke/TIA."		IIa A
"Addition of a concomitant surgical ablation procedure for AF does not change the incidence of late stroke/TIA, but subgroup analysis of nonrandomized controlled trials found a significant reduction in late stroke/TIA incidence."		IIa A, B-NR ^b
"A surgical procedure that includes concomitant surgical ablation for AF does improve HRQL."		IIa B-R

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"Addition of concomitant surgical ablation for AF does improve AF-related symptoms, and this improvement is greater than in patients without surgical ablation for AF."	IIa	C-LD
"Addition of concomitant surgical ablation for AF does improve 30-day operative mortality."	I	A
"Addition of a concomitant surgical ablation procedure for AF improves long term survival."	IIa	A, B-NR ^c

AF: atrial fibrillation; COR: class of recommendation; HRQL: health-related quality of life; LOE: level of recommendation; NR: nonrandomized; R: randomized; TIA: transient ischemic attack
a: "LOE A for deep sternal wound infection, pneumonia, reoperation for bleeding, and renal failure requiring dialysis; LOE B-R for intensive care unit length of stay and total hospital length of stay; and LOE B-NR for readmission less than 30 days and renal failure."
b: "LOE A for no change in incidence of late stroke/ TIA (up to 1 year of follow-up after surgery) and LOE B-NR for reduction in incidence of late stroke/TIA (>1 year of follow-up after surgery)."
c: "LOE A for no change in long-term survival (up to 1 year after surgery) and LOE B-NR for improvement in long-term survival (>1 year after surgery)."

Canadian Cardiovascular Society

In 2011, the Canadian Cardiovascular Society published guidelines on surgical therapy for AF. These guidelines stated there is a high rate of freedom from AF following surgical treatment (70%-85% at 1 year), but that surgical ablation of AF has not been shown to alter mortality rates (see Table 8).

Table 8. Guidelines on Surgical Therapy for Atrial Fibrillation

Recommendation	SOR	QOE
We recommend that a surgical AF ablation procedure be undertaken in association with mitral valve surgery in patients with AF when there is a strong desire to maintain sinus rhythm, the likelihood of success of the procedure is deemed to be high, and the additional risk is low.	Strong	Moderate

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We recommend that patients with asymptomatic lone AF, in whom AF is not expected to affect cardiac outcome, should not be considered for surgical therapy for AF.	Strong	Low
In patients with AF who are undergoing aortic valve surgery or coronary artery bypass surgery, we suggest that a surgical AF ablation procedure be undertaken when there is a strong desire to maintain sinus rhythm, the success of the procedure is deemed to be high, and the additional risk low.... This recommendation recognizes that left atrial endocardial access is not routinely required for aortic or coronary surgery.	Conditional	Low
We recommend that oral anticoagulant therapy be continued following surgical AF ablation in patients with a CHADS2 score ≥ 2 .	Strong	Moderate

AF: atrial fibrillation; QOE: quality of evidence; SOR: strength of recommendation.

Although not a formal recommendation, these guidelines indicated that stand-alone surgical ablation should be considered after failure of prior attempts at catheter ablation and antiarrhythmic drugs.

The Society (2012) published a focused update to its comprehensive 2010 guidelines on AF. The guidelines discussed the use of anticoagulants in the treatment of AF.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 9.



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Table 9. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02755688	Catheter Ablation Versus Thoracoscopic Surgical Ablation in Long Standing Persistent Atrial Fibrillation (CASA-AF)	120	Mar 2020
NCT04237389	Comparative Assessment of Catheter and Thoracoscopic Approaches in Patients With Persistent and Long-standing Persistent Atrial Fibrillation	60	Aug 2022
<i>Unpublished</i>			
NCT01319747 ^a	Video-Assisted Thoracoscopic Pulmonary Vein Isolation Versus Percutaneous Catheter Ablation in Atrial Fibrillation Trial	77	Nov 2014 (terminated)
	Success Trial		
NCT02047279	Left Atrium Reduction Versus no Left Atrium Reduction for Patients With Enlarged Left Atria and Persistent or Long Standing Persistent Atrial Fibrillation Undergoing Mitral Valve Surgery	120	Sep 2017 (completed)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Open and Thoracoscopic Approaches to Treat Atrial Fibrillation and Atrial Flutter (Maze and Related Procedures)”, 7.01.14, June 2020.

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08/09/2018 Medical Policy Committee review

08/15/2018 Medical Policy Implementation Committee approval. New policy

08/01/2019 Medical Policy Committee review

08/14/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/06/2020 Medical Policy Committee review

08/12/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2021

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	33254, 33255, 33256, 33265, 33266
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ICD-10 Diagnosis	I48.0-I48.92

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

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standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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